REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following remarks.

I. Status of the Claims

Claims 1-22, 24-30, 32-34 and 36-56 are currently pending in the application, with claims 1, 24-25, 32-33, 36 and 54-56 being the independent claims. Claims 23, 31 and 35 are canceled. Claims 1-22, 24-30, 32-34, 38 and 44-56 have been withdrawn from consideration pursuant to a Restriction/Election requirement. Thus, claims 36-37 and 39-43 are currently under consideration.

Claim 36 is amended to recite the proper name (ATP-gated ion channel purinergic receptor P2X7) of the acronym P2X7R. Support for the amendment to claim 36 may be found throughout the specification, including paragraph [0027] at page 3 and paragraph [0041] at page 4 of the published patent application. This amendment does not introduce any new matter into the application and its entry is respectfully requested.

II. The Claim Objection

The Office Action, at page 2, objects to claim 36 for reciting the acronym P2X7R. Without acquiescing to the propriety of the objection, the foregoing amends claim 36 to recite the proper name, ATP-gated ion channel purinergic receptor P2X7, of P2X7R. Thus, the objection is moot and its withdrawal is respectfully requested.

III. The Rejection Under 35 U.S.C. § 102

The Office Action, at pages 2-3, rejects claims 36-37 and 39-43 as allegedly being anticipated by U.S. Patent No. 6,323,236 B2 to McElroy. Applicants respectfully traverse this ground of rejection.

A. Summary of the Claimed Invention

The presently claimed invention is directed to a method of treating an *affective disorder* comprising administering a therapeutically effective amount of a pharmaceutical composition comprising a modulator of ATP-gated ion channel purinergic receptor P2X7 (P2X7R) activity to a subject suffering from the affective disorder.

As currently claimed, the affective disorder relates to major depression and the modulator of P2X7R is tenidap, a derivative thereof, or 3-substituted-2-oxindole-1-carboxamides.

B. McElroy Fails to Teach Each and Every Element of the Claimed Invention

McElroy discloses methods for the treatment and prevention of *Impulse Control Disorders (ICDs)* by administering *sulfamate derivatives* such as topiramate. ICDs are selected from the group consisting of intermittent explosive disorder (ED), kleptomania, pathological gambling, pyromania, trichotillomania, compulsive buying or shopping, repetitive self-mutilation, non-paraphilic sexual addictions, severe nail biting, compulsive skin picking, personality disorders with impulsive features, attention deficit/hyperactivity disorder, Binge Eating Disorder, bulimia nervosa, anorexia nervosa with binge eating and substance use disorders (*see* column 15, lines 52-60).

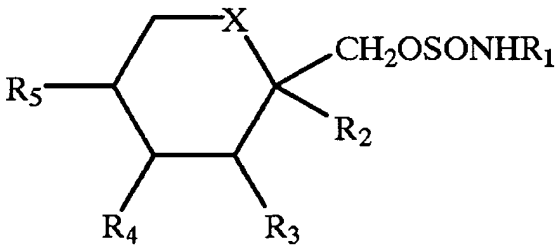
1. Impulse Control Disorders and Major Depression Are Different Diseases

The ICDs disclosed in McElroy and the major depression claimed in the present application are distinct medical indications, as evidenced by the classification provided in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR), published by the American Psychiatric Association and attached herein as Exhibit A.

DSM-IV-TR defines the various categories of mental disorders and provides diagnostic criteria for each mental disorder. Accordingly, major depression is classified as a mood disorder (*see* page 20 of DSM-IV-TR), whereas ICDs have their own classification, separate and distinct from mood disorders (*see* page 24 of DSM-IV-TR). In addition, with regard to Binge Eating Disorder, the DSM-IV-TR discloses that: "Overeating is frequently seen during episodes of Major Depressive Disorders but usually does not involved binge eating" (see Appendix B, page 787 of DSM-IV-TR). Thus, major depression is a different and distinguishable disease from ICDs, such as Binge Eating Disorder.

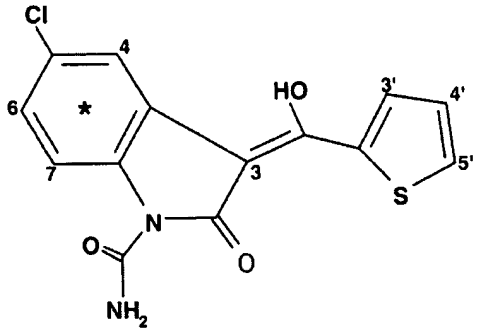
2. Sulfamate Derivatives Possess Different Chemical Structures from Tenidap

The sulfamate derivatives disclosed by McElroy have the following general formula:



where X is CH2 or oxygen; R1 is hydrogen or alkyl; and R2, R3, R4 and R5 are independently hydrogen, lower alkyl or are alkyl and are joined to form a cyclopentyl or cyclohexyl ring.

Tenidap, on the other hand, is a 3-substituted-2-oxindole-l-carboxamide and has the following structure:



Accordingly, the sulfamate derivatives disclosed by McElroy for the treatment of ICDs possess different chemical structures from tenidap and are therefore different compounds.

3. McElroy Fails to Teach Treatment of Major Depression with P2X7R Agonists

McElroy does not disclose in any way that P2X7R agonists can be used for the treatment of major depression. nor that tenidap is a P2X7R agonist, nor that tenidap can be used for the treatment of major depression.

McElroy only discloses that sulfamate derivatives may be used in conjunction with one or more other drug compounds selected from the group consisting of adrenergics, adrenocortical steroids, adrenocortical suppressants, aldosterone antagonists, amino acids, analeptics, analgesics, anorectic compounds, anorexics, anti-anxiety agents, antidepressants, antihypertensives, anti-inflammatory, antinauseants, antineutropenics, antiobsessional agents,

antiparkinsonians, antipsychotics, appetite suppressants, blood glucose regulators, carbonic anhydrase inhibitors, cardiotonics, cardiovascular agents, choleretics, cholinergics, cholinergic agonists, cholinesterase deactivators, cognition adjuvants, cognition enhancers, hormones, memory adjuvants, mental performance enhancers, mood regulators,. neuroleptics, neuroprotectives, psychotropics, relaxants, sedative-hypnotics, serotonin antagonists, serotonin inhibitors, serotonin receptor antagonists, stimulants, thyroid hormones, thyroid inhibitors, thyromimetics, cerebral ischemia agents, vasoconstrictors, and vasodilators (*see* columns 4-11 and claim 7). McElroy only lists Tenidap among the anti-inflammatory drugs that can be combined with sulfamate derivatives for the treatment of ICDs (*see* column 8, line 35). McElroy does not teach that tenidap can be used for the treatment of major depression as evidenced by the fact that McElroy provides an exhaustive list of antidepressant drugs (*see* column 6, line 35 to column 7, line 11) that does not include tenidap.

Therefore, at list for the reasons stated above, McElroy does not expressly nor inherently anticipate the claimed invention and the rejection is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

CONCLUSION

All of the stated grounds of objections and rejections have been properly traversed or rendered moot. Thus, the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date April 3, 2008

By [signature] Reg. No. 59,349

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